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K030346
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510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Date of preparation: April 30, 2003

1. Sponsor information

Name and address:	FMD, LLC 8382 C Terminal Road Lorton, VA 22079
Contact:	Yousry Faragalla, MD
Phone:	703-339-8881
Fax:	703-339-2922

2. Device information

Trade name:	Twinheads® TH-101 Extracorporeal Shock Wave Lithotripter
Common name:	Extracorporeal shock wave lithotripter
CFR Number:	21 CFR 876.5990 – Extracorporeal shock wave lithotripter
Product code:	78 LNS
Regulatory Class:	Class II (special controls)

3. Substantial Equivalence

The Twinheads® TH-101 ESWL is substantially equivalent to the following legally marketed devices:

- EDAP Technomed, Inc. - Sonolith Praktis (K003529)
- PCK Electronic Industry and Trade Co., Inc. – Stonelith V5 (K011106)

4. Device description

The Twinheads® TH-101 ESWL is a spark gap dual head shock wave lithotripter with an integrated fluoroscopy system for the fragmentation of kidney and ureteral calculi. The Twinheads® TH-101 delivers a pair of shock waves, which are separated from each other by a certain delay time, with perpendicular trajectories and overlapping focal zones. The pulse pairs or twin shocks are aligned with the calculi or stone utilizing the fluoroscopy system via two orientations.

A rapid current pulse discharges through a small gap in each of the two heads. The pulse discharge creates a shock wave, which radiates outward. Two identical ellipsoid reflectors serve to reflect and focus the shock waves, which are transmitted

into the patient by a water cushion through a membrane and contact gel. There are two shockwave sources and two cushions in the Twinheads® TH-101 ESWL.

Also included are an accurate motorized table and U-arm movements, high resolution fluoroscopy, and efficient shock wave energy sources.

5. Intended use

The Twinheads® TH-101 Extracorporeal Shock Wave Lithotripter is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

6. Technological characteristics

Shock wave characteristics are provided in the following table, which includes data for the minimum, typical, and maximum shock wave generator output settings.

Parameter	Min 7 kV	Typical 11 kV	MAX 14 kV
Peak-Positive Acoustic Pressure—(Mpa)	41.5	86.5	110
Peak-Negative Acoustic Pressure—(Mpa)	12.5	26.2	32.6
Rise Time (ns)	42	47	52
Compressional Pulse Duration (ns)	420	470	492
Maximum Focal Width (mm)	10.4	12.8	15.6
Orthogonal Focal Width (mm)	9.6	12.2	15.4
Focal Extent (mm)	28.4	30.6	31.4
Focal Volume (cm^3)	156	248	296
Distance between Focus & Target Location (mm) on Z Axis	1	5	6
Derived Acoustic Pulse Energy (mJ)	8.1	18.2	18.9
Derived Acoustic Pulse Energy at R= 4mm Radius (mJ)	40.1	51.2	55.4
Derived Acoustic Pulse Energy at R= 7mm Radius (mJ)	53.2	79.1	80.3

7. Clinical study

A confirmatory study as described in the FDA 510(k) guidance for ESWL was performed at two sites during which 20 patients were treated. The results of the study confirmed the functionality of the device and the adequacy of the proposed labeling. The safety and effectiveness of the device was also assessed through this study which concluded that the device was able to fragment stones successfully and not pose any unanticipated adverse effects. Therefore, the device has met the requirements for a confirmatory study as specified in the FDA Guidance Document.

8. Summary of nonclinical studies

The Twinheads® TH-101 conforms to the following consensus standards:

IEC 60601-2-36	Particular Requirements for Safety Equipment for Extracorporeally Induced Lithotripsy
IEC 61846	Ultrasonics- Pressure Pulse Lithotripters- Characteristics of Fields
IEC 60601-1-1	Medical Electrical Equipment Part 1-1, General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment Part 1-2, General Requirements for Safety Collateral Standard: Electromagnetic Compatibility Requirements and Tests
IEC 60601-1-3	Medical Electrical Equipment Part 1-3, General Requirements for Safety Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
IEC 60601-2-7	Medical Electrical Equipment Part 2-7, Particular Requirements for the Safety Of High-Voltage Generators of Diagnostic X-Ray Generators
IEC 60601-2-32	Medical Electrical Equipment Part 2-32, Particular Requirements for the Safety of Associated Equipment of X-Ray Equipment

9. Conclusion

The Twinheads® TH-101 Extracorporeal Shock Wave Lithotripter is substantially equivalent to legally marketed devices and conforms to the requirements of FDA's special controls document "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi", August 9, 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2003

Yousry Faragalla, M.D.
President
FMD, LLC
8382C Terminal Road
LORTON VA 22079

Re: K030346
Trade/Device Name: Twinheads® TH-101 Extracorporeal Shock Wave Lithotripter
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: January 30, 2003
Received: February 3, 2003

Dear Dr. Faragalla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030346

Device Name: Twinheads® TH-101 Extracorporeal Shock Wave Lithotripter

Indication for Use:

The Twinheads® TH-101 Extracorporeal Shock Wave Lithotripter is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-counter Use _____
(Per 21 CFR 801.109)

Carolyn Y Neuland (for Nancy Brogdon)
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030346